DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

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PURGED RJK

May 10, 1999

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 99 - 30

Dr. Eliot J. Huxley
President
Aurora Health Care, Inc
3000 W. Montana Avenue
Milwaukee, Wisconsin 53215

Re: 2103280004

Dear Dr. Huxley:

We are writing to you because on April 29, 1999, your facility, Aurora Health Center, 210 Wisconsin American Drive, Fond Du Lac, WI 54935, was inspected by a representative of the State of Wisconsin acting on behalf of the Food and Drug Administration (FDA). This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal law (the Mammography Quality Standards Act of 1992) (MQSA), your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following Level 1 finding at your facility:

Level 1

Radiologic technologist ~~~~~~ does not meet the requirement of being licensed by a State or certified by a FDA-recognized board.

The specific problem noted above appeared on your MQSA Facility Inspection Report which was issued to your facility at the close of the inspection.

Your site was previously cited for using an unqualified radiologic technologist during a 1998 inspection. Your site administrator was advised on this non-compliance via a May 14, 1998, Warning Letter. Based on an April 13, 1999, phone inquiry from your site's Mammography Supervisor to the Milwaukee FDA office, your site was verbally advised that an individual needed to have a valid ARRT Certificate to perform mammography. Despite these warnings the above named technologist was performing mammography on the day of the current inspection.

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they represent a serious violation of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, the Standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

It is necessary for you to act on this matter immediately. Please explain to this office in writing within 15 working days from the date you received this letter:

the specific steps you have taken to correct all of the violations noted in this letter; and
each step your facility is taking to prevent the recurrence of similar violations.

Please submit your response to Thomas W. Garvin, Radiological Health Specialist, Food and Drug Administration, 2675 N. Mayfair Rd., Milwaukee, WI 53226-1305.

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at http://www.fda.gov.

If you have more specific questions about mammography facility requirements or about the content of this letter please feel free to contact Mr. Garvin at (414) 771-7167 or tgarvin@ora.fda.gov.

Sincerely,

James A. Rahto
Director
Minneapolis District

TWG/ccl
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